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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,498	11/15/2000	Chaoying Zhao	014938.0003	4672

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/713,498

Applicant(s)

ZHAO, CHAOYING

Examiner

JOHN PAK

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-22, 25, 27, 28, 30 and 37-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 20-22, 25, 27, 28, 30 and 37-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 03292005.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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With the entry of applicant's amendments filed on 11/24/2004, claims 20-22, 25, 27, 28, 30 and 37-45 are now pending in this application.

Upon further review and reconsideration, *a posteriori*, a new lack of unity requirement is deemed to be necessary. The need for a new lack of unity requirement has developed during the examination of this application. See MPEP 811 and 1850.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 20-22, 25, 27-28, 30 and 37-45, drawn to a hypertonic pharmaceutical composition and method of preparation, wherein the "second substance" is hydroxyethyl starch.

Group II, claims 20, 25, 27, 37-41 and 45, drawn to a hypertonic pharmaceutical composition and method of preparation, wherein the "second substance" is PVP or N-2-hydroxypropylacrylamide.

Group III, claims 20, 25, 27, 37-41 and 45, drawn to a hypertonic pharmaceutical composition and method of preparation, wherein the "second substance" is dextran, carboxymethyl starch, sodium alginate, pentahydroxyethyl starch, gelatin "derivatives" or pectin.

Group IV, claims 20, 25, 27, 37-41 and 45, drawn to a hypertonic pharmaceutical composition and method of preparation, wherein the "second substance" is condense glucose, glucose, fructose or lactose.

Group V, claims 20, 25, 27, 37-41 and 45, drawn to a hypertonic pharmaceutical composition and method of preparation, wherein the "second substance" is glycerin, xylitol, propylene glycol or ethylene epoxide.

The inventions listed as Groups I, II, III, IV and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The term "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the invention, considered as a whole, makes over the prior art. See MPEP 1850. The prior art of record established during the prosecution of this application shows that hypertonic pharmaceutical compositions containing hydroxyethyl starch, without more, is not novel or nonobvious. See for example, Kramer et al. (US 4,908,350). Prior art such as Chemical abstracts 121:49804 establishes that the prior art is directed or limited to only a few (or one) specific second substances, and in the absence of nexus type teachings, the prior art recognizes the separate and distinct special technical features embodied by each separate and distinct "second substance."

Further, under Markush practice in PCT Rule 13.2, the alternatives for "second substance" must meet two criteria for there to be same or corresponding technical

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features among the inventions. Here, even though all alternatives have a common property, there is no common structure and there is no recognized class of chemical compounds to which the various alternatives belong. The various alternatives for the second substance are all structurally divergent from one another, even within each group, and therefore, no same or corresponding special technical feature can be found among the five invention groups.

For these reasons, the five inventions as set forth above are not so linked as to form a single general inventive concept. Consequently, the five inventions lack a unity of invention and the present restriction requirement is deemed to be necessary and proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

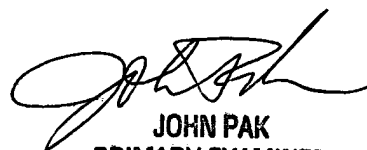
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN PAK
PRIMARY EXAMINER
GROUP 1600